

ATTN: BOX PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Chandrashekar, Ramaswamy
Morales, Tony H.

Serial No.: Not Yet Assigned

Filed: January 22, 2002

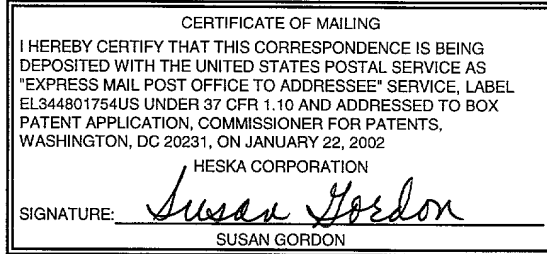
Atty. File No.: HW-8-2

For: "PARASITIC HELMINTH CUTICLIN
PROTEINS AND USES THEREOF"

) Group Art Unit:

) Examiner:

) PRELIMINARY AMENDMENT



Box Patent Application
Commissioner for Patents
Washington, DC 20231

Dear Sir:

Prior to the initial review of the above-identified patent application by the Examiner,
please enter the following Preliminary Amendment.

IN THE SPECIFICATION

On page 1, please delete the title of the invention and insert therefor --PARASITIC
HELMINTH CUTICLIN PROTEINS AND USES THEREOF--.

On page 1, following the title of the invention, please insert the following --This
Application is a Divisional Application of co-pending Application Serial No. 09/812,642, filed
March 20, 2001, which is a Divisional of Application Serial No. 09/323,427, filed June 1, 1999,
which issued as U.S. Patent No. 6,248,329 B1 on June 19, 2001, each entitled "PARASITIC
HELMINTH CUTICLIN NUCLEIC ACID MOLECULES AND USES THEREOF"--.

IN THE CLAIMS

Please cancel Claims 1-20 without prejudice to or disclaimer of the subject matter thereof.

Please add Claims 21-36 as follows:

21. An isolated *Dirofilaria immitis* protein, wherein said *Dirofilaria immitis* protein is encoded by a nucleic acid molecule that hybridizes under conditions comprising (a) hybridizing in a solution comprising 17.53 grams of sodium chloride and 8.82 grams sodium citrate in 0.1 liters of water, pH 7 (2X SSC) in the absence of nucleic acid helix destabilizing agents, at a temperature of 37°C, and (b) washing in a solution comprising 8.765 grams of sodium chloride and 4.41 grams sodium citrate in 0.05 liters of water, pH 7 (1X SSC) in the absence of nucleic acid helix destabilizing agents at a temperature of 64°C, to a nucleic acid sequence selected from the group consisting of SEQ ID NO:2, SEQ ID NO:5, SEQ ID NO:7 and SEQ ID NO:10.

22. The protein of Claim 21, wherein said protein comprises an amino acid sequence that is at least about 95% identical to an amino acid sequence selected from the group consisting of SEQ ID NO:4 and SEQ ID NO:9, wherein determination of percent identity between molecules is made by a DNAsis™ computer program, using default parameters.

23. The protein of Claim 21, wherein said protein is encoded by a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:6 and SEQ ID NO:8.

24. The protein of Claim 21, wherein said protein comprises an amino acid sequence selected from the group consisting of SEQ ID NO:4 and SEQ ID NO:9.

25. An isolated antibody that selectively binds to a protein as set forth in Claim 21.

26. A method to identify a compound capable of inhibiting filariid cuticlin activity, said method comprising contacting an isolated *Dirofilaria immitis* cuticlin protein as set forth in Claim 21, with a putative inhibitory compound under conditions in which, in the absence of said compound, said protein has cuticlin activity, and determining if said putative inhibitory compound inhibits said activity.

27. A composition comprising an excipient and a compound selected from the group consisting of: (a) an isolated *Dirofilaria immitis* protein, wherein said *Dirofilaria immitis* protein is encoded by a nucleic acid molecule that hybridizes under conditions comprising (a) hybridizing in a solution comprising 17.53 grams of sodium chloride and 8.82 grams sodium citrate in 0.1 liters of water, pH 7 (2X SSC) in the absence of nucleic acid helix destabilizing agents, at a temperature of 37°C, and (b) washing in a solution comprising 8.765 grams of sodium chloride and 4.41 grams sodium citrate in 0.05 liters of water, pH 7 (1X SSC) in the absence of nucleic acid helix destabilizing agents at a temperature of 64°C, to a nucleic acid sequence selected from the group consisting of SEQ ID NO:2, SEQ ID NO:5, SEQ ID NO:7 and SEQ ID NO:10; and (b) an isolated antibody that selectively binds to a protein having an amino acid sequence selected from the group consisting of SEQ ID NO:4 and SEQ ID NO:9.

28. The composition of Claim 27, wherein said composition further comprises a component selected from the group consisting of an adjuvant and a carrier.

29. The composition of Claim 27, wherein said protein comprises an amino acid sequence that is at least about 95% identical to an amino acid sequence selected from the group consisting of SEQ ID NO:4 and SEQ ID NO:9, wherein determination of percent identity between molecules is made by a DNAsis™ computer program, using default parameters.

30. The composition of Claim 27, wherein said protein is encoded by a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:6 and SEQ ID NO:8.

31. The composition of Claim 27, wherein said protein comprises an amino acid sequence selected from the group consisting of SEQ ID NO:4 and SEQ ID NO:9.

32. A method to inhibit molting of filariid larvae in an animal, said method comprising administering to said animal a composition comprising a compound selected from the group consisting of: (a) an isolated *Dirofilaria immitis* protein, wherein said *Dirofilaria immitis* protein is encoded by a nucleic acid molecule that hybridizes under conditions comprising (a) hybridizing in a solution comprising 17.53 grams of sodium chloride and 8.82 grams sodium citrate in 0.1 liters of water, pH 7 (2X SSC) in the absence of nucleic acid helix destabilizing agents, at a temperature of 37°C, and (b) washing in a solution comprising 8.765 grams of sodium chloride and 4.41 grams sodium citrate in 0.05 liters of water, pH 7 (1X SSC) in the absence of nucleic acid helix destabilizing agents at a temperature of 64°C, to a nucleic acid sequence selected from the group consisting of SEQ ID NO:2, SEQ ID NO:5, SEQ ID NO:7 and SEQ ID NO:10; and (b) an isolated antibody that selectively binds to a protein having an amino acid sequence selected from the group consisting of SEQ ID NO:4 and SEQ ID NO:9.

33. The method of Claim 32, wherein said composition further comprises a component selected from the group consisting of an excipient, an adjuvant and a carrier.

34. The method of Claim 32, wherein said protein comprises an amino acid sequence that is at least about 95% identical to an amino acid sequence selected from the group consisting

of SEQ ID NO:4 and SEQ ID NO:9, wherein determination of percent identity between molecules is made by a DNAsis™ computer program, using default parameters.

35. The method of Claim 32, wherein said protein is encoded by a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:6 and SEQ ID NO:8.

36. The method of Claim 32, wherein said protein comprises an amino acid sequence selected from the group consisting of SEQ ID NO:4 and SEQ ID NO:9.

REMARKS

Applicants hereby authorize the filing fee of \$370 to be charged to Deposit Account No. 081930 for this Divisional application. Please debit any underpayment or credit any overpayment to Deposit Account No. 081930.

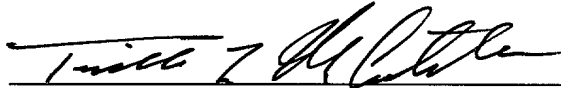
The Sequence Listing in this Divisional application is identical to the computer readable form and paper form of the Sequence Listing that was submitted in the parent application, Serial No. 09/323,427, filed June 1, 1999. For the Examiner's convenience, Applicants enclose a paper and diskette copy of the Sequence Listing for the present divisional application, which are identical copies of the paper and computer readable forms of the Sequence Listing (SEQ ID NO:1 through SEQ ID NO: 18) submitted on June 1, 1999 in the priority application Serial No. 09/323,427.

Pending Claims 21-36 of the application are believed to be in condition for allowance. Favorable consideration and early allowance of the application is earnestly requested. In the

event the Examiner has any questions regarding this application, the Examiner is invited to contact the undersigned attorney at (970)493-7272.

Respectfully submitted,

Dated: January 22, 2002



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

On page 1, the title of the invention was amended as follows: --PARASITIC HELMINTH CUTICLIN ~~NUCLEIC ACID MOLECULES~~ PROTEINS AND USES THEREOF--.

On page 1, following the title of the invention, the following paragraph was inserted -- This Application is a Divisional Application of co-pending Application Serial No. 09/812,642, filed March 20, 2001, which is a Divisional of Application Serial No. 09/323,427, filed June 1, 1999, which issued as U.S. Patent No. 6,248,329 B1 on June 19, 2001, each entitled "PARASITIC HELMINTH CUTICLIN NUCLEIC ACID MOLECULES AND USES THEREOF"--.

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36. The method of Claim 32, wherein said protein comprises an amino acid sequence selected from the group consisting of SEQ ID NO:4 and SEQ ID NO:9.